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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,288	02/26/2002	Anthony C. Vrba	1001.1541101	4123

28075 7590 09/30/2004

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT PAPER NUMBER

3736

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,288	VRBA ET AL.	
	Examiner	Art Unit	
	Brian Szmaj	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6-28-02; 7-11-03</u> . | 6) <input type="checkbox"/> Other: ____. |

Claim Objections

1. Claim 1 is objected to because of the following informalities: In line 5 of the claim, "couple" should read as "coupled" in order to be grammatically correct.
Appropriate correction is required.
2. Claim 2 is objected to because of the following informalities: In line 1, "said actuatable tip" appears it should read as either "said actuatable stop" or "said actuator" since an actuateable tip has not been disclosed in Claim 1. Appropriate correction is required.
3. Claim 16 is objected to because of the following informalities: The claim contains Dacron, which is a trademarked name, and therefore cannot be claimed. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-10 and 17-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Levinson et al (6,277,139).

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Levinson et al disclose a vascular protection and embolic material retriever and further disclose an elongated core wire having a longitudinal axis, a proximal end and a distal end; an actuatable stop disposed at the distal end of the core wire, the actuatable stop moveable between a collapsed position and an expanded position; an actuator couple to the stop, the actuator moveable between a first position and a second position to move the stop between the collapsed position and the expanded position; a filter disposed on the core wire; the actuatable stop comprises a tubular member having a proximal end and a distal end; the distal section of said tubular member includes a plurality of circumferentially disposed openings adapted to permit a plurality of struts disposed therebetween to expand in an outward direction; the inner diameter of the tubular member is substantially similar to the outer diameter of the core wire; the inner diameter of the tubular member is larger than the outer diameter of the core wire; a locking mechanism adapted to prevent relative motion between the actuatable stop and the core wire; the locking mechanism comprises an enlarged outer diameter portion disposed on the core wire; the locking mechanism comprises an enlarged outer diameter portion disposed on the core wire corresponding in size and shape to a reduced inner diameter portion disposed on the actuatable stop; the locking mechanism comprises a locking hub disposed about a proximal portion of the core wire; and an actuator disposable about the core wire, the actuator having a proximal end and a distal end. See Column 6, lines 21-37; Column 7, lines 31-67; Column 9, lines 47-53; Column 12-20; Column 12, lines 48-51; and Column 13, lines 33-36.

6. Claims 23-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubrul et al (6,602,265).

Dubrul et al disclose an intravascular tissue separation method and further disclose providing an articulating guidewire comprising an elongated core wire having a longitudinal axis, a proximal end and a distal end; and an actuatable stop disposed at the distal end of the core wire, the actuatable stop moveable between a collapsed position and an expanded position; inserting the guidewire into the lumen of a blood vessel; positioning a distal portion of the guidewire beyond a lesion or other protrusion within the body; actuating the actuatable stop from the collapsed position to the expanded position; advancing a filter on the guidewire to the stop; advancing an intravascular device along the core wire until the intravascular device abuts the outwardly expanded stop; an actuator moveable about the core wire, said actuator having a proximal end and a distal end; and inserting the guidewire into the lumen of a blood vessel. See Column 7, lines 15-23 and 51-67; Column 8, lines 13-15; and Column 14, lines 1-8 and 44-54.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levinson et al (6,277,139) as applied to claim 10 above, and further in view of Dubrul et al (6,602,265).

Levinson et al, as discussed above, disclose a vascular protection and embolic material remover but fail to disclose the actuatable stop comprises a polymeric tube; the actuatable stop comprises a mesh sleeve; and the mesh sleeve comprises Dacron.

Dubrul et al, as discussed above disclose an intravascular tissue separation device and further disclose the actuatable stop comprises a polymeric tube; the actuatable stop comprises a mesh sleeve; and the mesh sleeve comprises Dacron. See Column 7, lines 15-23 and 51-67; Column 8, lines 13-15; and Column 14, lines 1-8 and 44-54.

Since both Levinson et al and Dubrul et al disclose intravascular devices that remove material, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Levinson et al to include the use of a polymeric tube or a polymeric mesh sleeve, as per the teachings of Dubrul et al, since it is well known in the art to utilize many biocompatible materials on intravascular devices, including metals as well as polymeric materials.

9. Claims 11, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levinson et al (6,277,139) as applied to claim 10 above, and further in view of Tate (3,841,308).

Levinson et al, as discussed above, disclose a vascular protection and embolic material retriever but fail to disclose the actuatable stop comprising a spring coil; a spring coil helically disposed about the core wire; and the polymeric tube is accordion-shaped.

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Tate discloses a distally valved catheter device and further discloses the actuatable stop comprising a spring coil; a spring coil helically disposed about the core wire; and the polymeric tube is accordion-shaped. See Figures 2, 4 and 6-8.

Since both Levinson et al and Tate disclose catheter devices, it would have been obvious to one of ordinary skill in the art to modify the device of Levinson et al to include the use of a spring coil and have the polymeric tube be accordion-shaped, as per the teachings of Tate, since it is well known to provide a helical coil about the distal end of a guidewire device as well as a polymeric tube that has the ability to be accordion-shaped.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (703) 308-3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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